

§ 73.2329

21 CFR Ch. I (4–1–14 Edition)

§ 73.2329 Guanine.

(a) *Identity and specifications.* (1) The color additive guanine shall conform in identity and specifications to the requirements of § 73.1329 (a)(1) and (b).

(2) Color additive mixtures of guanine may contain the following diluents:

(i) For coloring cosmetics generally, only those diluents listed under § 73.1001(a)(1);

(ii) For coloring externally applied cosmetics, only those diluents listed in § 73.1001(b) and, in addition, nitrocellulose.

(b) *Use and restrictions.* The color additive guanine may be safely used in cosmetics generally, including cosmetics intended for use in the area of the eye, in amounts consistent with good manufacturing practice.

(c) *Labeling requirements.* The color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any information required by law, labeling in accordance with the provisions of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification pursuant to section 721(c) of the act.

[42 FR 37537, July 22, 1977]

§ 73.2396 Lead acetate.

(a) *Identity.* The color additive lead acetate is the trihydrate of lead (2+) salt of acetic acid. The color additive has the chemical formula $\text{Pb}(\text{OOCCH}_3)_2 \cdot 3\text{H}_2\text{O}$.

(b) *Specifications.* Lead acetate shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Water-insoluble matter, not more than 0.02 percent.

pH (30 percent solution weight to volume at 25 °C), not less than 4.7 and not more than 5.8.

Arsenic (as As), not more than 3 parts per million.

Lead acetate, not less than 99 percent.

Mercury (as Hg), not more than 1 part per million.

(c) *Uses and restrictions.* The color additive lead acetate may be safely used in cosmetics intended for coloring hair on the scalp only, subject to the following restrictions:

(1) The amount of the lead acetate in the cosmetic shall be such that the lead content, calculated as Pb, shall not be in excess of 0.6 percent (weight to volume).

(2) The cosmetic is not to be used for coloring mustaches, eyelashes, eyebrows, or hair on parts of the body other than the scalp.

(d) *Labeling requirements.* (1) The label of the color additive lead acetate shall conform to the requirements of § 70.25 of this chapter, and bear the following statement or equivalent:

Wash thoroughly if the product comes into contact with the skin.

(2) The label of the cosmetic containing the color additive lead acetate, in addition to other information required by the act, shall bear the following cautionary statement, conspicuously displayed thereon:

CAUTION: Contains lead acetate. For external use only. Keep this product out of children's reach. Do not use on cut or abraded scalp. If skin irritation develops, discontinue use. Do not use to color mustaches, eyelashes, eyebrows, or hair on parts of the body other than the scalp. Do not get in eyes. Follow instructions carefully and wash hands thoroughly after each use.

(e) *Exemption from certification.* Certification of this color additive for the prescribed use is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

[45 FR 72117, Oct. 31, 1980, as amended at 72 FR 10357, Mar. 8, 2007]

§ 73.2400 Pyrophyllite.

(a) *Identity and specifications.* The color additive pyrophyllite shall conform in identity and specifications to the requirements of § 73.1400 (a)(1) and (b).

(b) *Uses and restrictions.* Pyrophyllite may be safely used for coloring externally applied cosmetics, in amounts consistent with good manufacturing practice.